

Food and Drug Administration, HHS

§ 862.2

- 862.2320 Beta or gamma counter for clinical use.
- 862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.
- 862.2485 Electrophoresis apparatus for clinical use.
- 862.2500 Enzyme analyzer for clinical use.
- 862.2540 Flame emission photometer for clinical use.
- 862.2560 Fluorometer for clinical use.
- 862.2570 Instrumentation for clinical multiplex test systems.
- 862.2680 Microtitrator for clinical use.
- 862.2700 Nephelometer for clinical use.
- 862.2720 Plasma oncometer for clinical use.
- 862.2730 Osmometer for clinical use.
- 862.2750 Pipetting and diluting system for clinical use.
- 862.2800 Refractometer for clinical use.
- 862.2850 Atomic absorption spectrophotometer for clinical use.
- 862.2860 Mass spectrometer for clinical use.
- 862.2900 Automated urinalysis system.
- 862.2920 Plasma viscometer for clinical use.
- 862.3650 Opiate test system.
- 862.3660 Phenobarbital test system.
- 862.3670 Phenothiazine test system.
- 862.3680 Primidone test system.
- 862.3700 Propoxyphene test system.
- 862.3750 Quinine test system.
- 862.3830 Salicylate test system.
- 862.3840 Sirolimus test system.
- 862.3850 Sulfonamide test system.
- 862.3870 Cannabinoid test system.
- 862.3880 Theophylline test system.
- 862.3900 Tobramycin test system.
- 862.3910 Tricyclic antidepressant drugs test system.
- 862.3950 Vancomycin test system.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 16122, May 1, 1987, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 862 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 862.1 Scope.

(a) This part sets forth the classification of clinical chemistry and clinical toxicology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required in § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

[52 FR 16122, May 1, 1987, as amended at 67 FR 58329, Sept. 16, 2002; 78 FR 18233, Mar. 26, 2013; 79 FR 50552, Aug. 25, 2014]

§ 862.2 Regulation of calibrators.

Many devices classified in this part are intended to be used with a calibrator. A calibrator has a reference

Subpart D—Clinical Toxicology Test Systems

- 862.3030 Acetaminophen test system.
- 862.3035 Amikacin test system.
- 862.3040 Alcohol test system.
- 862.3050 Breath-alcohol test system.
- 862.3080 Breath nitric oxide test system.
- 862.3100 Amphetamine test system.
- 862.3110 Antimony test system.
- 862.3120 Arsenic test system.
- 862.3150 Barbiturate test system.
- 862.3170 Benzodiazepine test system.
- 862.3200 Clinical toxicology calibrator.
- 862.3220 Carbon monoxide test system.
- 862.3240 Cholinesterase test system.
- 862.3250 Cocaine and cocaine metabolite test system.
- 862.3270 Codeine test system.
- 862.3280 Clinical toxicology control material.
- 862.3300 Digitoxin test system.
- 862.3320 Digoxin test system.
- 862.3350 Diphenylhydantoin test system.
- 862.3360 Drug metabolizing enzyme genotyping system.
- 862.3380 Ethosuximide test system.
- 862.3450 Gentamicin test system.
- 862.3520 Kanamycin test system.
- 862.3550 Lead test system.
- 862.3555 Lidocaine test system.
- 862.3560 Lithium test system.
- 862.3580 Lysergic acid diethylamide (LSD) test system.
- 862.3600 Mercury test system.
- 862.3610 Methamphetamine test system.
- 862.3620 Methadone test system.
- 862.3630 Methaqualone test system.
- 862.3640 Morphine test system.
- 862.3645 Neuroleptic drugs radioreceptor assay test system.